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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,777	12/29/2000	Hiroyuki Morimoto	2500.6	3913

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FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER	
TRAN, SUSAN T	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/647,777	MORIMOTO ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-53,63-70 and 72-102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-53,63-70 and 72-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 44 is objected to because of the following informalities: the phrase "compressed at tableting pressure than 1.3 ton/cm^2" in lines 5-6 appears to be a typographical error.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42-53, 63-70 and 72-102 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It appears that applicant's specification does not provide support for the limitations "coating film which is destroyed when a molding material comprising said granule is compressed at tableting pressure greater than 1.3 ton/cm^2"; "a base matrix... is destroyed when a molding material comprising said granule is compressed at tableting pressure greater than 1.3 ton/cm^2"; "said molding material comprises same amount of said granule and said diluting agent; and "said molding material is dry". In accordance with MPEP §

714.02, applicant should specifically point out support for any amendment made to the disclosure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 42-53, 63-70 and 72-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morimoto et al. EP 0 650 826 A1, in view of Roche US 5,075,114.

Morimoto teaches a tablet compressing method using tabletting machine with lubricant spraying mean (see abstract). The method comprising spraying lubricant uniformly on the surface of an upper punch, a lower punch, and a die, filling the die with pharmaceutical materials, and compressing the pharmaceutical material to form a drug tablet (columns 2-3 and columns 5-7).

Morimoto does not teach the specific form of pharmaceutical material being claimed, such as, coated granule or granule in a matrix base. Nonetheless, Morimoto teaches that his tabletting method can be used for tabletting many kinds of tablets such as powdered or granular medicine, and so on (column 7, lines 34-38).

Roche teaches a medicament tablet comprising granules coated with polymers blend (see abstract and column 2, lines 45-60). The resulting coated granules were then compressed into tablet form using tabletting machine having die wall and punches

(columns 9-10). Thus, it would have been obvious for one of ordinary skill in the art to modify the pharmaceutical materials to be tabletted in Morimoto using the coated drug granule in view of the teaching of Roche, because the references teach the use of compressed tabletting machine to compress pharmaceutical materials.

Claims 42-53, 63-70 and 72-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsushima et al. US 6,036,974, in view of Roche US 5,075,114.

Tsushima teaches a method for preparation of tablet comprises preparing the tabletting material containing medicines and excipients, coating on the surface of the tabletting material a lubricant, coating the surface of the punches with lubricant, filling the die with the coated tabletting material, and compressing to obtain tablet (columns 2 and 6).

Tsushima does not teach the specific form of pharmaceutical material being claimed, such as, coated granule in a matrix base.

Roche teaches a medicament tablet comprising granules coated with polymers blend (see abstract and column 2, lines 45-60). The resulting coated granules were then compressed into tablet form using tabletting machine having die wall and punches (columns 9-10). Thus, it would have been obvious for one of ordinary skill in the art to modify the tabletting materials of Tsushima using the coated drug granule in view of the teaching of Roche, because the references teach the use of compressed tabletting machine to compress pharmaceutical materials.

It is noted that the reference is silent as to the teaching of the percent amount of lubricant being coated onto the surface of the die and punches. However, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable amount of lubricant to obtain a smooth surface tablet. As well as the dividing line on the tablet, it would have been obvious for one of ordinary skill in the art, because dividing line, groove line, marking line, or scored tablet is well known in pharmaceutical art. Moreover, absent of evident on the contrary, the burden is shifted to applicant to provide data showing the amount of surfactant uses by the cited references do not fall within the claimed range.

Response to Arguments

Applicant's arguments filed 10/24/06 have been fully considered but they are not persuasive.

Applicant argues that Morimoto does not disclose a molding material without lubricant.

However, it is noted at column 1, lines 43-49, Morimoto teaches using tabletting machine with outer lubricant spray type does not need to mix the lubricant with the

pharmaceutical material. Therefore, the quality of the tablet can be improved. Accordingly, Morimoto does suggest a molding material without lubricant.

Applicant argues that Roche does not teach or suggest selecting coating film that is destroyed when compressed at tabletting pressure greater than 1.3 ton/cm^2. Applicant further indicated that Roche teaches the coated granules are mixed with magnesium stearate lubricant.

In response to applicant's arguments, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Although Roche mentioned the use of magnesium stearate as a lubricant, Roche specifically teaches that the lubricant is used to lubricate the dye walls and punches of the tabletting machine. Roche is cited in combination with Morimoto, where Morimoto teaches using outer lubricant to avoid mixing the lubricant with the tabletting material to improve the quality of the tablet. Thus, one of ordinary skill in the art would have been motivated to prepare a tablet taught by Roche using the outer lubricant tabletting method of Morimoto to obtain the claimed invention. Moreover, although the independent claims recite "molding material not containing any lubricant", the dependent claims further added other materials

including diluting agent. It is known in pharmaceutical art that dilute agent such as talc[1] which is known also known as a lubricating agent.

Regarding the limitation "coating film that is destroyed when compressed at tabletting pressure greater than 1.3 ton/cm^2", the burden is shifted to applicant to show that the coating film taught by Roche is not destroyed when compressed at tabletting pressure greater than 1.3/cm^2.

Applicant argues that Tsushima cannot be utilized with Roche's coated particle, because when 10% by weight ethanol or water is added to Roche's coated granule, the structure of granule is destroyed by the ethanol or the water. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Roche teaches the use of a coating composition that also comprises organic solvent such as methanol, ethanol and the like (column 4, lines 14-28). It is noted that the active granule taught by Tsushima is intimately mixed with an organic solvent containing a coating polymer such as polyvinyl pyrrolidone or hydroxypropyl cellulose. Therefore, the burden is shifted to applicant to

[1] Papp et al. (US 6,265,445); column 15, lines 51-54.

show detrimental effect in the present of organic solvent in the coated granule of Roche.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SUSAN TRAN
PRIMARY EXAMINER

Art Unit 1615